

Summary of Key Conformity Assessment Activities and Examples of U.S. Programs

NIOSH Public Meeting
PPT Conformity Assessment
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Richard W. Metzler
Senior Scientist
NPPTL, Office of the Director

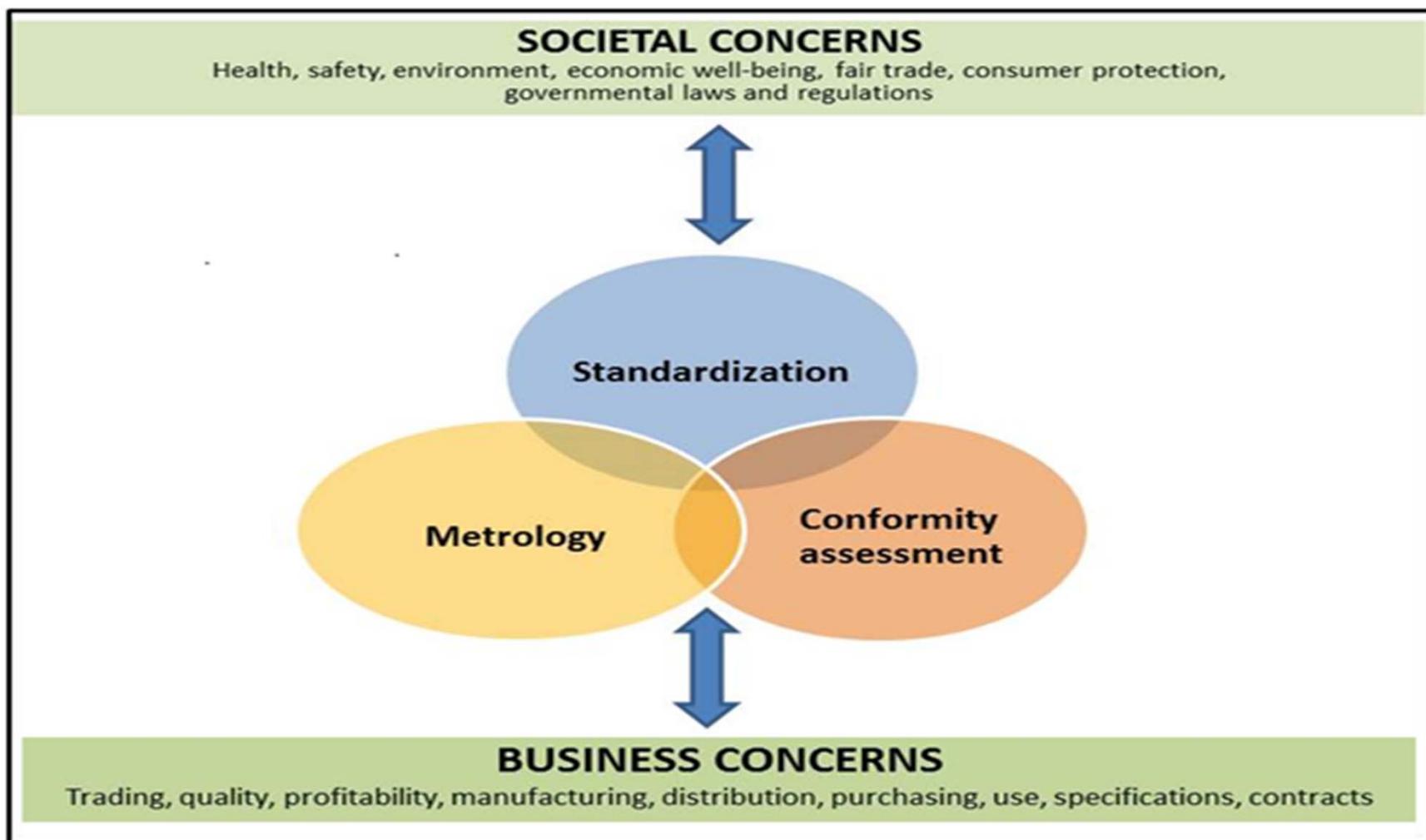
Conformity Assessment

“Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled” ISO/IEC 17000:2004

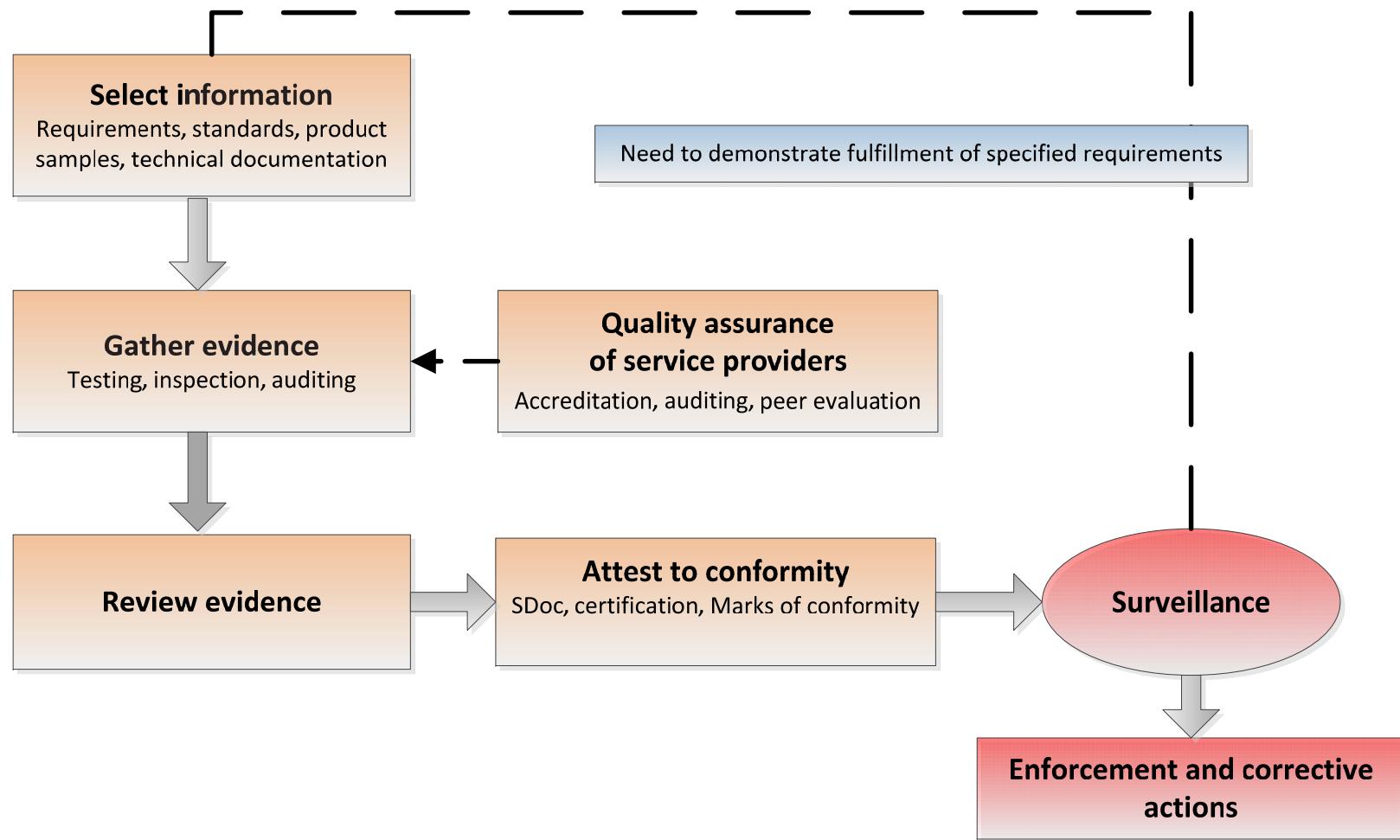
Conformity assessment Vocabulary and general principles

- Provide consumers with added confidence
- Give the company a competitive edge
- Help regulators ensure that health, safety or environmental conditions are met

Conformity Assessment in a Quality Infrastructure



Functional Approach to Conformity Assessment



ISO Conformity Assessment

Committee on Conformity Assessment (CASCO)

- ▶ **Develops policy and publishes standards**
 - Promote mutual recognition and acceptance of national and regional conformity assessment systems, and the appropriate use of International Standards for testing, inspection, certification, assessment and related purposes
 - Published 28 conformity assessment standards
 - Participating countries: 71 – ANSI is US representative
 - Observing countries: 48

ISO Conformity Assessment

- ▶ **Main forms of conformity assessment**
 - Certification - ISO/IEC 17065 – 2012, Requirements for bodies certifying products, processes and services
 - Inspection - ISO/IEC 17020 – 2012, Requirements for the operation of various types of bodies performing inspection
 - Testing - ISO/IEC 17025 – 2005, General requirements for the competence of testing and calibration laboratories

ISO Conformity Assessment

► Main forms of conformity assessment (cont.)

- Accreditation - ISO/IEC 17011- 2004, General requirements for accreditation bodies accrediting conformity assessment bodies
- Surveillance - ISO/IEC 17011, ISO/IEC 17065
ISO/IEC 17020
- Supplier's Declaration of Conformity - ISO/IEC 17050,
Part 1: General requirements
Part 2: Supporting documentation

ISO Conformity Assessment

- ▶ **Main forms of conformity assessment (cont.)**
 - Quality management systems - ISO/9001 – 2008
Requirements for a quality management system to demonstrate the ability to provide products that fulfill customer and applicable regulatory requirements
 - Registration - ISO/IEC 17021 – 2011, Requirements for bodies providing audit and certification of management systems

U.S. PPT Conformity Assessment

- ▶ A uniform comprehensive program does not exist
- ▶ Consensus standards do not typically contain CA requirements (ANSI, ASTM)
- ▶ OSHA basic health and safety requirements “incorporate by reference” U.S. consensus standards
- ▶ Consequently, supplier's declaration of conformity with no third-party verification or follow-up market surveillance and enforcement is the norm

U.S. PPT Conformity Assessment

- ▶ Current CA programs are product-directed and designed primarily for products that protect workers against serious (medium to high) hazards
- ▶ Consequently, both private and public sectors apply CA requirements in different ways to like hazard levels

Examples:

- NIOSH (respirators) and NIJ (bomb suits)
- NFPA (fire and emergency services products)

42CFR84 NIOSH Respirator Conformity Assessment Activities



Certification Activities

- Engineering Evaluation
- Respirator Testing
- QA Plan Evaluation



Post Market Activities

- Manufacturing Site Audits
- Respirator Product Audits
- Respirator Evaluations

Thursday
June 8, 1995

Part II

Department of Health and Human Services
Public Health Service
42 CFR Part 84

Department of Labor
Mine Safety and Health Administration
30 CFR Parts 11, 49, 56, 57, 58, 70, 72, and 75

Department of Labor
Mine Safety and Health Administration
Department of Health and Human Services
Centers for Disease Control and Prevention

Respiratory Protective Devices; Final Rules and Notice

federal register

NIJ/DOJ/Office of Justice Programs Public Safety Bomb Suit

- ▶ **NIJ Standard – 0117.00 Public Safety Bomb Suit Standard, March 2012**
 - Voluntary performance standard providing for one level of protection
 - Defines both performance requirements and the methods used to test performance
 - “Incorporates by references” national and international standards (NFPA, MIL, ANSI, ASTM, EDA, IEC, CSA)

NIJ/DOJ/Office of Justice Programs Public Safety Bomb Suit

- ▶ NIJ CR – 0117.00 Public Safety Bomb Suit Certification Program Requirements, March 2012
 - Certification (ISO/IEC Guide 65) with additional NIJ requirements (e.g. surveillance frequencies, safety alerts, product recalls, independent third parties for testing and inspections)
 - Testing (ISO/IEC 17025)
 - Inspections (ISO/IEC 17020)
 - Quality management system (ISO 9001)
 - Registration (ISO/IEC 17021)

NFPA - Fire and Emergency Services Conformity Assessment

- ▶ **13 PPT and PPE product standards apply Certification (Chapter 4) requirements**
 - Third-party certification (ISO/IEC 17065)
 - Notified body accreditation (ISO/IEC 17011)
 - Inspection and testing (ISO/IEC 17025)
 - Annual recertification
 - Manufacturer's quality assurance program (ISO-9001)
 - Registration (ISO/IEC 17021)
 - Investigation of hazards (ISO Guide 27)
 - Manufacturer's investigation of complaints and returns
 - Manufacturer safety alert and product recall systems

U.S. PPT Conformity Assessment

- ▶ Existing PPT CA programs in the U.S. represent a wide diversity of approaches
- ▶ Current requirements for pre-market CA and post market surveillance and enforcement varies across products intended for like levels of hazard
- ▶ Merger of private and public sector CA programs could form a national framework to deliver a uniform comprehensive program providing confidence in a standard level of protection for workers

Quality Partnerships Enhance Worker Safety & Health



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Thank you!